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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,142	07/19/2000	W. Ray Knowles	Knowles/HairLoss	1598

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/619,142	KNOWLES, W. RAY	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application

1. The prosecution for the instant application is reopened due to the most recent 131 declaration (second 131 declaration filed June 24 2002) where applicant swore behind the 102(e) rejection over Crandall(earliest US filing date: October 19,1995) and Roentsch (earliest US filing date: March 24,1995). The previous rejections based on Crandall or Roentsch references are withdrawn due to 2nd 131 declaration that antedates the cited references' earliest US filing date. Additionally, prosecution is reopened to state a deficiency(i.e. new matter) found which was not mentioned previously during the prosecution. The instant office action supercedes all the previous office actions of the record.

2. Acknowledgement is made of 2nd 131 declaration filed June 24, 2002 and petition request which has been granted on July 27, 2002.

3. Acknowledgement is made of amendment filed January 10, 2002. Claims 1-5, 7-16 and 18-22 are pending and presented for prosecution on the merits.

New matter

4. The amendment filed Jan. 10, 2002 (see paper no. 20) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

Claim Rejections - 35 USC § 112

1. Claims 1-5, 7-16 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added material that is not supported by the original disclosure is as follows: In claims 1 and 12, the newly added limitation "a non-retinoid penetration enhancer" is not supported by the original disclosure. It is noted that applicant can not exclude the subject matter that is not considered as the applicant's invention at the time of application filed. Thus, the examination will be continued based on the "a penetration enhancer" that was required by original claims (before the said change).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibson (US 5015470).

Gibson teaches a topical composition for maintaining and increasing hair growth comprising minoxidil and penetration enhancer (see abstract, table 1 and column 4, lines 40-42). It further teaches that the penetration enhancer potentiates the benefit of the chemical (i.e.minoxidil) by improving its the delivery through the stratum corneum to the site of action in the immediate environment

of the hair follicle (see column 14, lines 1-15). The effective penetration enhancers (e.g. propylene glycol, oleyl alcohol) for the minoxidil compounds are taught by this reference, where the efficacy was proven and well documented in this patent as well (see Tables and examples, columns 20-26). All the critical elements are taught by the reference, and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

7. Claims 1-4 and 12-15 re rejected under 35 U.S.C. 102(b) as being anticipated by Bazzano (US 5183817).

Bazzano teaches a method of increasing the rate of hair growth, stimulation of hair follicles to produce new hair growth, prolongation of the anagen phase of the hair cycle, conversion of vellus hair to growth as terminal hair, and treatment of alopecia, using a pharmaceutically and cosmetically effective topical composition comprising a combination of minoxidil (0.01-30%, see example 1 at column 21) and retinoid, and beneficial additives such as antiandrogen (e.g. progesterone) which blocks testosterone conversion effectively as an active ingredient in a vehicles such as ethanol and propylene glycol, see the entire abstract and text, especially columns 3, lines 60 thru column4, lines 11 &19-20; and entire claims 1-28, especially claim 28. Bazzano further teaches that the patented composition containing minoxidil (or minoxidil type compounds) in combination with retinoids (or mixtures thereof) is synergistically effective in stimulating or increasing the rate of hair growth. Bazzano teaches that minoxidil is effective in prolonging the life of keratinocytes and slows senescence in addition to somewhat effective in producing new vellus

hair growth and sparse terminal hair growth, see column 3-4. Bazzano emphasizes that the weak hair growth activity of minoxidil can be enhanced by making synergistic combination with retinoid due to its penetration enhancing activity and its own pharmacological effects on hair growth. For instance, Bazzano specifically states that the problems associated with the topical composition containing said active agent (e.g. minoxidil) in influencing hair growth is obtaining by good percutaneous absorption of active compounds wherein the retinoid compounds cause excellent percutaneous absorption of themselves and other compounds used in combination therewith and are very active on the keratinizing cells of the skin, including the hair follicles." -(see column 19, lines 36-42 and column 22, lines 18-65). Since Bazzano teaches and uses the retinoid as a penetration enhancer in his invention to improve efficacy of the penetration to the active working site including hair follicle, the claims are met by the cited reference. It is also noted that progesterone is inherently 5-alpha reductase inhibitor (as evidenced by Orentreich et al. US 5053403, column 2, lines 10-15). Furthermore, Bazzano teaches pharmacodynamically active vehicles such as alcohols (i.e. propylene glycol and ethanol), see column 19, lines 60-67 and formulation examples I&II. It has been well known and recognized by any skilled artisan in the art that propylene glycol and ethanol has penetration enhancing activity wherein these agents are naturally potentiating the ability of penetration of said active agents (i.e. minoxidil and progesterone) in addition to the penetration enhancing activity of retinoid.

All the critical elements are taught by the cited reference and the claimed subject matter is not patentably distinct.

8. Claims 1-2, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Zupan(US 4,440,777).

Zupan teaches a progesterone in combination with eucalyptol for treating alopecia wherein eucalyptol is used as a penetration enhancer to deliver the active agent(e.g. progesterone) to the targeted site effectively without toxic side effect, see abstract ; column 3, lines 17-35; and column 6, lines 37-43. All the critical elements required by the instant claims are taught by the cited reference, and thus, the claimed subject matter is not patentably distinguished from the cited reference's teaching.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2, 4-5, 7-10, 13, 15-16, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson (US 5,015,470) in view of Bazzano (US 5183817) or Schostarez (US 5,373,012).

Gibson's teaching is mentioned in 102 rejection (Supra).

Applicant's claims differ because Gibson fails to teach 5 alpha reductase inhibitor as an additive.

However, it would have been obvious to one of ordinary skill in the art to add beneficial additives (i.e. 5 alpha reductase inhibitor) at the time of the invention made when Gibson's teaching is taken in view of Bazzano's or Schostarez's teaching Because Each patentee (Bazzano or Schostarez) teaches that minoxidil composition can be admixed with 5 alpha reductase inhibitor to enhance its therapeutic efficacy.

As mentioned in 102 rejection (supra), Bazzano teaches that minoxidil and retinoid with 5 alpha reductase inhibitor such as progesterone in a vehicle (e.g. propylene glycol, ethanol), see 102 rejection above.

Schostarez also teaches that minoxidil analog (5-fluoro minoxidil) is admixed with minoxidil and/or 5 alpha reductase inhibitor (i.e. finasteride) beneficially. Schostarez also teaches that penetration enhancers (e.g. oleyl alcohol) can be effectively added to enhance its penetration so that the active ingredient can be delivered to the site of action (hair follicle) effectively, see column 4, lines 45 thru column 5, lines 15.

Thus, one would have been motivated to modify these teachings together to formulate the most effective topical composition wherein the enhanced therapeutic efficacy is achieved by delivering the active agents into the site of action efficiently and lowering the therapeutic dose of each component via utilizing different biological pathway and potentiating other component's activity

so that one could have maximized therapeutic efficacy while reducing the unwanted side effect, which usually associated with high therapeutic dose used.

The article of manufacture including the said composition and label for its cosmetic and pharmaceutical advantages(intended use), the specific dosage amount and ratio required by the instant claims 5,7-10,16 and 18-21 have been considered to be within the scope of these references because each active ingredient is well known and documented in the art, where the effective dosages required by the instant claims are considered to be within the therapeutic dosage range known to any ordinary skilled artisan, and because the minor variations including the selection of optimal dosages or variable applications in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious. Applicant's claims 8-10, 19-21 differ in that they require informational means instructing the reader in the cosmetic or pharmaceutical use of the said combination to maintain healthy hair or to induce hair growth. Judicial notice is taken that the packaging and labeling instructing use of a composition is old and well known, for example, see Rogain® (minoxidil 2%) and the label therein. Especially, the use of each active ingredient in separate or in combination is well known in the art as evidenced by the cited references above. The difference between the claimed and prior art articles is the printed matter on the label or other informational means indicating the intended use(already known) of the composition. However, the printed matter on the label or other informational means does not possess a "functional relationship" with the article of manufacture and is, accordingly, not granted any patentably

weight. Thus, the claimed invention would have been obvious to one of ordinary skill in the art at the time of applicant's invention made. One would have been motivated to include the context specifying its advantages on the label to increase marketability and industrial value.

3. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (US 5183817) in view of Grollier et al(US 6,333,057).

As aforementioned immediately above, Bazzano teaches that minoxidil and retinoid with 5 alpha reductase inhibitor such as progesterone in a vehicles(e.g. propylene glycol, ethanol), see 102 rejection above.

Applicant's claims differ because they require a sunscreen.

However, it would have been obvious to one of ordinary skill in the art to add the sunscreen to the Bazzano's hair growth composition when Bazzano is taken in view of Grollier et al because Grollier et al teach the addition of sunscreen into the topical hair growth formulation; see claims and examples.

One would have been motivated to add the sunscreens into the topical hair growth composition comprising minoxidil, 5α-reductase inhibitor and penetration enhancer, with reasonable expectation of success because the sunscreen protects the hair from damage of lackluster, discoloration or fading due to the sun, particularly U.V light. And also the sunscreen may retard and protect the scalp of alopecia subjects which is directly exposed to the possibly adverse effects of UV radiation in addition to , in the case of some of the

sunscreen agents, improved solubilization of the minoxidil to be obtained as suggested in Grollier's reference, see Grollier's patent: column 2, lines 2-15.

Thus, one would have been motivated to do so because adding sunscreen into a hair growth composition improves cosmetic appeal and pharmaceutical quality as suggested in the cited reference.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

Conclusion

1. No claim is allowed.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner

February 11, 2003
Art unit 1614

Marianne Seidel
Supervisory Primary Patent examiner

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